K022384

SEP 17 2002

510 (K) SUMMARY

Date of Summary

July 19, 2002

Product Name:

PocketChem™UA
AUTION Stick 10TA

Sponsor & Manufacturer:

ARKRAY, Inc.
57 NISHI AKETA-CHO, HIGASHI-KUJO
MINAMI-KU, KYOTO, 601-8045, JAPAN
FDA Registration #: 961144

US Distributor

Thermo BioStar
331 S. 104th Street
Louisville, CO 80027

Correspondent:

Fran White
MDC Associates
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device:

Product: Clinitek 50 / MULTISTIX 10SG Reagent Strips
Manufactured by: Bayer Corp
510k Number: K960546

Product Description:

Automated urine chemistry analyzer – a urinalysis system for the measurement of certain physical properties and chemical constituents of urine.

Intended Use:

PocketChem™UA is a urine chemistry analyzer intended for the simultaneous detection of multiple chemistry analytes in urine. PocketChem™UA is intended for use in routine urinalysis – for the semi-qualitative detection of glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite and leukocytes in urine at the following levels of detection:

Analyte	Level of Detection
Glucose	50 mg/dL – 1000 mg/dL
Protein	15 mg/dL – 1000 mg/dL
Bilirubin	0.5 mg/dL – Over (>6 mg/dL)
Urobilinogen	2 mg/dL – Over (>8 mg/dL)
pH	5.0 – 9.0
Specific Gravity	<1.005 – >1.030
Blood (Hemolysis and Non Hemolysis)	0.06 mg/dL – 1.0 mg/dL
Ketones	5 mg/dL – 150 mg/dL
Nitrite	NEG – 2+
Leukocytes	25 Leu/µL – 500 Leu/µL

ARKRAY PocketChem™UA and AUTION Sticks 10TA are intended for professional use only.

Performance Characteristics:

ARKRAY PocketChem™UA and AUTION Stick 10 TA System detect 10 analytes measured in routine urinalysis.

ARKRAY PocketChem™ and AUTION Stick 10TA is substantially equivalent to the Clinitek 50 and MULTISTIX 10SG Reagent Strips manufactured by Bayer Corporation 510k number K960546.

Product performance was compared to the Bayer System (Clinitek50 & MULTISTIX 10SG). Three hundred and two (302) clinical samples were tested for routine urinalysis. 30 positive samples were found for glucose and 60 positive for blood.

In comparison to the Bayer system, ARKRAY was proven to correlate results of 97.7% for Glucose and 100% for Blood for both negative and positive samples. The manual read of the AUTION Sticks 10TA compared to the PocketChem™UA System in correlated 100% of the samples.

Reproducibility and precision was evaluated using control-matrix samples spiked with varying concentrations of glucose and blood; throughout the entire range of detection, including extreme negative and positive samples. The results confirmed the reproducibility and precision of the ARKRAY PocketChem™UA and the AUTION Sticks 10TA.

Conclusion:

ARKRAY PocketChem™UA and AUTION Sticks 10TA are substantially equivalent as an automated system and as manual-read strips to Bayer's Clinitek 50 and MULTISTIX 10SG Reagent Strips (K960546) as an automated urinalysis system and reagent strips for visual interpretation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 2002

Arkray, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k022386
Trade/Device Name: PacketChem™UA & AUTION Stick 10TA
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL; JIP; KQO
Dated: July 19, 2002
Received: July 22, 2002

Dear Ms. White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number:
Device Name: **PocketChem™UA & AUTION Stick 10TA**

Indication for Use:
The PocketChem™UA is a urine chemistry analyzer and is intended for use with the AUTION Sticks 10TA for the determination of glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite and leukocytes in urine. The tests provided by the use of the PocketChem™UA and the AUTION Sticks 10TA are considered routine urinalysis at the following levels of detection:

Analyte	Level of Detection
Glucose	50 mg/dL – 1000 mg/dL
Protein	15 mg/dL – 1000 mg/dL
Bilirubin	0.5 mg/dL – Over (>6 mg/dL)
Urobilinogen	2 mg/dL – Over (>8 mg/dL)
pH	5.0 – 9.0
Specific Gravity	<1.005 – >1.030
Blood (Hemolysis and Non Hemolysis)	0.06 mg/dL – 1.0 mg/dL
Ketones	5 mg/dL – 150 mg/dL
Nitrite	NEG – 2+
Leukocytes	25 Leu/µL – 500 Leu/µL

For professional use only.

Jean Cooper

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510(K022386

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**